

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

IDIL ISSAK,)	
)	
Plaintiff,)	
)	
v.)	No. 3:25-cv-238
)	
RANDY BOYD, PRESIDENT OF THE)	
UNIVERSITY OF TENNESSEE)	Judge Crytzer
SYSTEM, in his Official Capacity, <i>et al.</i> ,)	Magistrate Judge McCook
)	
Defendants.)	

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

When humans study other humans with no oversight, history teaches that atrocities may occur. Ex. 1, Belmont Report, at 1. To protect human research subjects, the Department of Health and Human Services (HHS) and approximately seventeen other federal departments and agencies require that all federally funded research created to contribute to generalizable knowledge be approved by institutional review boards (IRB) responsible for ensuring the research minimizes risks and protects human rights. 45 C.F.R. §§ 46.101-124.¹ Federal regulations and ethical principles obligate the University of Tennessee (UT or the University) to review all qualifying research at UT, regardless of the source of funding. 28 C.F.R. § 46.103(b)(1); Belmont Report, at 4; Ex. 2, UT's FWA, at 1. IRB review proceeds in two steps—first, IRB staff conduct a preliminary review to ensure that the research proposal is complete and ready for review by the full IRB; second, the full IRB committee will review and vote on whether to approve, modify, or reject the proposal.

Plaintiff Idil Issak, an anthropology Ph.D. student at UT, intends to conduct human-subjects research overseas. Specifically, she plans to interview vulnerable Ethiopian women who serve as domestic laborers in the United Arab Emirates. Issak, moreover, hopes to use these interviews to produce scholarship that will “contribute to generalizable knowledge.” 45 C.F.R. § 46.102(l). This means that she must go through UT's IRB-review process. To that end, Issak submitted her research proposal to the IRB several times. Issak, though, never made it past step one of IRB review. Each time, the IRB staff deemed her proposal incomplete, requested clarification about various aspects of her research, and asked her to resubmit. Rather than continue this iterative process, however, Issak decided to try a different path to get her research approved—she sued UT, arguing that the IRB-

¹ See 6 C.F.R. Pt. 46 (DHS), 7 C.F.R. Pt. 1c (USDA), 10 C.F.R. Pt. 745 (DOE), 14 C.F.R. Pt. 1230 (FAA), 15 C.F.R. Pt. 27 (DOC), 16 C.F.R. Pt. 1028 (FTC), 20 C.F.R. Pt. 431 (SSA), 22 C.F.R. Pt. 225 (DOS), 24 C.F.R. Pt. 60 (HUD), 28 C.F.R. Pt. 46 (DOJ), 29 C.F.R. Pt. 21 (DOL), 32 C.F.R. Pt. 219 (DOD), 34 C.F.R. Pt. 97 (ED), 38 C.F.R. Pt. 16 (VA), 40 C.F.R. Pt. 26 (EPA), 45 C.F.R. Pt. 690 (NSF), 49 C.F.R. Pt. 11 (DOT).

review process violates her First Amendment rights and imposes an unconstitutional condition.

Federal pleading rules require dismissal when a plaintiff “can[not] construct a claim from the events [alleged] in the complaint.” *16630 Southfield Ltd. v. Flagstar Bank, F.S.B.*, 727 F.3d 502, 504 (6th Cir. 2013) (citation omitted). This is one of those cases, and this Court should dismiss Issak’s Amended Complaint. First, this Court lacks jurisdiction. A key Defendant is protected by sovereign immunity and Issak has failed to establish standing. Second, setting aside these threshold jurisdictional obstacles, Defendants are protected from suit by the statute of limitations and qualified immunity. Finally, Issak’s claims also fail on the merits. The IRB-review process regulates conduct, not speech, so heightened First Amendment review is unwarranted. And even if the process did implicate Issak’s First Amendment rights, it would easily satisfy heightened scrutiny. Accordingly, it is also not an unconstitutional condition. The Amended Complaint should be dismissed.

BACKGROUND

I. Federal Regulatory Framework

The IRB-review process has deep roots. In 1946 an international military tribunal “tried and convicted Nazi doctors who conducted horrific unethical experiments” on prisoners. *Why Regulations*, HHS (Oct. 16, 2023), <https://tinyurl.com/ynz6j82k>. This led to creation of the “Nuremberg Code, a set of international guidelines for conducting research with humans.” *Id.* Later incidents showed that the Nuremberg Code was not enough. Public outcry after an infamous syphilis study in Tuskegee, Alabama, in which government doctors studied the “evolution of untreated syphilis in poor African American men” while actively preventing them “from learning their diagnosis,” inspired Congress to create an advisory committee to study the necessary ethical principles for research with human subjects. *Id.* That committee wrote the Belmont Report, which describes these ethical principles and advises how to implement them. *Id.* A “general rule,” the Belmont Report provides, is that “if there is any element of research in an activity, that activity should undergo review for the protection of human

subjects.” Belmont Report, at 4.

After the Belmont Report, Congress enacted 42 U.S.C. § 289, which requires institutions that receive federal funding for research involving human subjects to assure the federal government that the research will be reviewed by an IRB. HHS regulations guide these institutions on the makeup and operation of IRBs, 45 C.F.R. §§ 46.101-124. For research taking place abroad, HHS IRB protections merely supplement foreign law. 45 C.F.R. § 46.101(g)-(h). States may also provide additional IRB protections. *Id.* § 46.101(f). At least seventeen federal agencies have followed HHS’s example and adopted IRB-review requirements for the research they fund. *Supra* p. 1 n.1.

HHS regulations detail an IRB’s duties and scope of review. An IRB must “review proposed research” and vote to approve it. 45 C.F.R. § 46.108. An IRB may require modifications or disapprove a proposal. 45 C.F.R. § 46.109. Before approving research, an IRB must apply a strict set of criteria that minimizes risks for human subjects, and an IRB must give special review to research with vulnerable subjects like “economically or educationally disadvantaged persons.” 45 C.F.R. § 46.111. Institution officials may further review, and even reject, proposals an IRB approves, but they cannot approve what the IRB rejected. 45 C.F.R. § 46.112.

For many years, HHS regulations explained IRB approval was required if research with human subjects consisted of “systematic investigation . . . designed to develop or contribute to generalizable knowledge.” 45 C.F.R. § 46.102(d) (2017). To provide greater clarity “about how to interpret which activities were covered,” 82 Fed. Reg. 7149-01, 7172 (Jan. 19, 2017), HHS amended the rule to “explicitly remove[]” a category of activities, such as “scholarly and journalistic activities,” that “focus directly on the specific individuals about whom information are collected.” *Id.* at 7174. It did so because, for the removed “activities, the ethical requirement is to provide an accurate and evidence-based portrayal of the individuals involved, and not necessarily to protect them from public scrutiny.” *Id.*; 45 C.F.R. § 46.102(l)(1).

Because UT conducts eligible research that receives federal funding, it must comply with these regulations. 45 C.F.R. §§ 46.101(a), 46.102(f); Ex. 3, UT SOPs, at 16. This means that UT must register its IRB with HHS's Office for Human Research Protections (OHRP) and fill out an application known as a Federal-wide assurance (FWA), which states that UT fully complies with federal requirements. 45 C.F.R. § 46.103; UT SOPs, at 17-18. FWAs are designed to assure *all* federal departments and agencies of a state institution's compliance with all federal requirements, so FWAs are structured to comply with all federal regulations—not just HHS regulations. *FWA Instructions*, HHS (July 31, 2017), <https://tinyurl.com/sczaf4t2>. For example, DOJ requires that institutions provide a “statement of principles” that govern human-subjects research at the institutions “regardless of whether the research is subject to federal regulation.” 28 C.F.R. § 46.103(b)(1). Thus, the FWA requires institutions to list the “ethical principles” that govern *all* their human-subjects research, regardless of how it is funded. *FWA Instructions*, HHS (July 31, 2017), <https://tinyurl.com/sczaf4t2>. UT relies on the Belmont Report for its governing principles. UT FWA, at 1; UT SOPs, at 15.

If UT were to violate its FWA, the consequences would be severe. OHRP surveils for institutional compliance. *OHRP Organization*, HHS (Mar. 3, 2016), <https://tinyurl.com/ywuk9k8z>. If a researcher engages in misconduct, OHRP asks the institution to investigate and report, and may take further action if needed to correct the situation. *Id.* When necessary, OHRP has suspended *all* federally funded research at a university. *VCU officials work to reinstate research*, VCU News (Jan. 19, 2000), <https://perma.cc/6AVX-VEAR>; Letter from OHRP to University of Texas (Sept. 14, 2000), <https://perma.cc/KAD2-6JHV>. Misconduct during a single study can be enough to trigger an OHRP investigation. Letter from OHRP to NYSPI (June 23, 2023), <https://perma.cc/JPL6-KLG9>. OHRP can also terminate federal funding for noncompliance. 45 C.F.R. § 46.123. That sort of termination could be especially disastrous given other recent funding losses. *Colleges and Universities Cut Costs Over Funding Freezes*, Best Colleges.com (July 8, 2025), <https://perma.cc/PP6B-NDRV>. UT also has the

independent duty to promptly report risks to human subjects and “serious or continuing noncompliance” with federal requirements. 45 C.F.R. § 46.108(a)(4)(i); UT SOPs, at 151-52, 157.

UT has made great effort to comply with federal regulations. It created a Human Research Protection Program (HRPP) that includes an IRB. *HRPP - Research, Integrity and Assurance*, UTK.edu, <https://perma.cc/KQ9C-SLD3> (last accessed Aug. 8, 2025); UT SOPs at 20. UT created detailed, publicly available SOPs that explained how the IRB-review process works at UT. *See For Researchers*, UTK.edu, <https://research.utk.edu/research-integrity/human-research-protection-program/for-researchers/> (last accessed Aug. 8, 2025) (click the option labeled “SOPs”).

At its simplest, UT’s IRB review has two parts. It starts with a preliminary review by IRB staff to ensure an application is complete and ready for full review by the IRB. UT SOPs, at 64. Once an application is complete, the full IRB committee will review and vote on whether to approve, modify, or reject it. *Id.* at 22, 64-65. For international research, UT’s IRB “may require additional verification and information from people outside the particular projects who are familiar with the customs, practices, or standards of care” of the region and can assure the IRB that the project does not conflict with international law or local culture and social norms. *Id.* at 235-36. This commonly takes the form of a “written review,” *id.* at 236, which UT refers to as a “memo” or “letter” of “cultural appropriateness,” Ex. 4, Submissions Packet, at 16, 48.

Adhering to the Belmont Report’s general rule, all human-subjects research connected with UT must go through IRB review, regardless of the project’s source of funding. UT SOPs, at 8, 18, 32. UT staff will consult the IRB Chair and HRPP Director to determine whether “an activity constitutes human subjects research.” *Id.* at 32.

In sum, IRB review at UT serves four primary purposes. First, it is required by UT’s FWA due to the general rule in the Belmont Report. 28 C.F.R. § 46.103; UT FWA, at 1; Belmont Report, at 4. Second, it protects human research subjects, and especially vulnerable subjects. Belmont Report, at 9.

Third, it protects the unique rights of foreign research subjects. UT SOPs, at 235-36. Fourth, it is a pedagogical tool that teaches students how to “respect . . . the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of” the University. UT SOPs, at 8.

II. Parties and Posture

Idil Issak is a student at UT pursuing an Anthropology Ph.D. She has sued the IRB, as well as twelve UT officials, because she believes subjecting her dissertation to IRB review violates the First Amendment. Amend. Compl., Dkt. 34 ¶¶ 1-12, 16-28. Prior to applying to UT’s doctoral program, Issak worked in the UAE “where she witnessed foreign female domestic workers suffering human rights abuses.” *Id.* at ¶¶ 33-34. She applied to UT’s doctoral program to research and write “about the mental and physical burdens” of the “enslaved and/or abused” Ethiopian workers in the UAE. *Id.* at ¶¶ 34-36. Issak completed much of the work needed to obtain a degree, including receiving approval of her dissertation proposal. *Id.* at ¶¶ 44-56. But to write her dissertation, she still needs to travel to the UAE and interview Ethiopian domestic workers. *Id.* at ¶¶ 57, 128. Because her research involves both human subjects and a systematic investigation by which she hopes to contribute to generalizable knowledge, she must go through IRB review. *Id.* at ¶¶ 69-78, 131. Issak, however, has yet to get past the preliminary review for completeness. *Id.* at ¶ 79; UT SOPs, at 64.

Issak first applied for IRB review on February 29, 2024, with the support of her then-advisor Raja Swamy. Dkt. 34 ¶¶ 48, 79; Submissions Packet, at 1-45. Issak explained that she planned to interview Ethiopian women in the UAE, to provide in-depth insights into their lives, and to capture “broader implications for policy and social justice.” Submissions Packet, at 10, 18. Her application highlighted the “vulnerability” of these women, who operate with difficult racial, gender, and cultural dynamics; may come from poorer “socio-economic backgrounds”; and potentially have limited education. *Id.* at 10-15, 25, 27. She first asked for expedited review of her application. *Id.* at 9. The

IRB Chair, Defendant Lora Beebe, responded to Issak on March 25, 2024, explaining that expedited review was unavailable because the study posed “greater than minimal risk” to its vulnerable subjects. *Id.* at 46. In light of those risks, Beebe asked Issak to provide more information to complete her submission, including a clarification in the memo of cultural appropriateness about whether Issak needed approval from a UAE ethics committee. *Id.* at 46-48.

Issak submitted a revised application on April 24, 2024. *Id.* at 1, 49-116. Beebe responded on May 17, 2024, reiterating that the application could not be expedited and requesting modifications, including clarification in the memo of cultural appropriateness about whether review by a UAE ethics committee was required. *Id.* at 117-19; Dkt. 34 ¶ 85. Issak then reached out to Beebe and explained she would only be conducting research in emirates that did not require review by an ethics committee, and Beebe thanked Issak for clarifying where she would be conducting her research. Ex. 5, Beebe and Issak Email Chain – May 2024, at 3-4; Dkt. 34 ¶¶ 87-88. Issak followed up with Beebe, and Beebe “meant to ask” Issak, yet again, to revise her memo of cultural appropriateness to indicate that Issak did not require approval from a UAE ethics committee. Beebe and Issak Email Chain – May 2024, at 1-2. However, Beebe mistook Issak for a different student, resulting in a confusing response. *Id.* Issak then accused Beebe of lacking “the aptitude to process [Issak’s] application,” reported the situation to Beebe’s supervisor, and railed against Beebe for “continu[ing] under this false belief that” UAE required an ethics committee to review her research. *Id.*; Dkt. 34 ¶¶ 90-91. On May 31, 2024, Beebe again explained that if Issak’s research did not need approval from a UAE ethics committee, then her memo of cultural appropriateness had to be revised to clearly state this. Submissions Packet, at 120; Dkt. 34 ¶¶ 91-93.

Issak submitted a third application on June 3, 2024, which—for the first time—clarified that her research would occur in emirates that do not have official research protocols. Submissions Packet, at 1, 139. She also included a memo of cultural appropriateness that clarified, for the first time, that

her research did not need approval from a UAE ethics committee. *Id.* at 185-86; Dkt. 34 ¶ 95. Given that clarification, Beebe no longer had questions about the cultural appropriateness of the proposed research. Submissions Packet, at 192-94; Dkt. 34 ¶ 97. But other issues remained. Beebe requested further clarifications and additions to complete the application, including revisions to the project synopsis, the participant recruitment process, and the investigator's plan for protecting the subject's confidential information. Submissions Packet, at 192-94; Dkt. 34 ¶ 97. Issak submitted a fourth application on July 1, 2024, Submissions Packet, at 1, 195-269; Dkt. 34 ¶ 79. This application did not address many of Beebe's concerns and resulted in the HRPP Director, Defendant Rob Withrow setting up a meeting with Issak on July 23, 2024, to explain how she could improve her research plan. Submissions Packet, at 362-65; Dkt. 34 ¶ 98. Beebe then asked Issak to amend her application to track the changes discussed in her meeting with Withrow. Submissions Packet, at 270.

Issak submitted a fifth application on August 1, 2024. This application had a markedly different tone from the others—several of Issak's responses appeared in bold, enlarged, underlined, red text and all-caps. Submissions Packet, at 271-361; Dkt. 34 ¶ 79. Withrow responded to this application and explained in detail how Issak could amend her application to address what was requested at the July 23, 2024 meeting, including revisions to the project synopsis, the participant recruitment process, and the investigator's plan for protecting the subject's confidential information. Submissions Packet, at 362-65; Dkt. 34 ¶¶ 98-100. He reminded Issak of the need to keep her communications professional. Submissions Packet, at 362. He also suggested that, because Issak's proposal was so undeveloped, it appeared to lack a systematic-investigation methodology. *Id.* at 362-65. He did not have any concerns about the project's cultural appropriateness. *Id.*

In the following months, Issak prepared this lawsuit. Dkt. 34 ¶¶ 104-108. After filing this lawsuit, Issak continued to pursue IRB review. In this pursuit, she decided to submit a sixth application on July 1, 2025, that not only omitted edits recommended by her former advisor Swamy but outright

violated his request that she not submit anything without his approval. *Id.* ¶¶ 108-16; Ex. 6, Swamy and Issak Email Chain – June 2025; Submissions Packet, at 1, 366-469. Once she did this, Issak asked for a new advisor. Dkt. 34 ¶ 115. After learning what Issak had done, Swamy notified the IRB that the submission was made without his approval. *Id.* at ¶ 116. Withrow then responded to this application, explaining that the IRB could not review any application for completeness until Issak had obtained approval from a new advisor. *Id.* at ¶ 118; Submissions Packet, at 470. Issak does not allege any further attempts to submit a complete application.

Issak sues under 42 U.S.C. § 1983. Dkt. 34 ¶ 13. In her five-count Amended Complaint, Issak divides her claims by defendant type rather than legal issue. *Id.* at ¶¶ 127-77 Issak alleges the IRB-review process is an unconstitutional content- and speaker-based restriction on her speech; the cultural-appropriateness requirement is an unconstitutional viewpoint-based restriction on her speech; the IRB-review process is a facially unconstitutional prior restraint that chills speech; and the IRB-review process imposes an unconstitutional condition on her speech. *Id.* Issak has sued the IRB, Beebe, Withrow, and ten additional UT officials—Randy Boyd, Donde Plowman, Marieke Van Puymbroeck, Deborah Crawford, Brad Day, Graciela Cabana, Patrick Grzanka, Michael Blum, Barbara Heath, and Tami Wyatt. *Id.* at ¶¶ 16-28. She sues all UT officials in their official capacities, and also sues Grzanka, Blum, Heath, Beebe, Withrow, and Wyatt, in their individual capacities. *Id.* She brings all claims against all Defendants, including official- and individual-capacity Defendants. *Id.* at ¶¶ 205-267. She asks for declaratory and injunctive relief as well as nominal damages. *Id.* at 46-47.

LEGAL STANDARD

I. Lack of Subject Matter Jurisdiction

Rule 12(b)(1) “provides for the dismissal of an action for lack of subject matter jurisdiction,” and plaintiffs bear “the burden of establishing that subject matter jurisdiction exists.” *Cartwright v. Garner*, 751 F.3d 752, 759-60 (6th Cir. 2014). “Subject matter jurisdiction is always a threshold

determination.” *Am. Telecom Co. v. Republic of Lebanon*, 501 F.3d 534, 537 (6th Cir. 2007). Two key doctrines limit a court’s jurisdiction: sovereign immunity and standing. *Food & Drug Admin. v. All. for Hippocratic Med. (Alliance)*, 602 U.S. 367, 379 (2024); *S & M Brands, Inc. v. Cooper*, 527 F.3d 500, 507-09 (6th Cir. 2008). When presented with a factual attack on jurisdiction in a Rule 12(b)(1) motion, a district court may “properly consider[] evidence outside the pleadings to resolve [a] jurisdictional question.” *Ames v. LaRose*, 86 F.4th 729, 731 (6th Cir. 2023).

II. Failure to State a Claim

For a Rule 12(b)(6) motion, the court must “construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff.” *Wesley v. Campbell*, 779 F.3d 421, 428 (6th Cir. 2015) (quoting *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007)). “However, ‘a legal conclusion couched as a factual allegation’ need not be accepted as true on a motion to dismiss, nor are recitations of the elements of a cause of action sufficient.” *Fritz v. Charter Twp. of Comstock*, 592 F.3d 718, 722 (6th Cir. 2010) (quoting *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir. 2009)).

ARGUMENT

The Amended Complaint should be dismissed for two reasons. First, the Court lacks jurisdiction because Issak does not overcome the IRB’s sovereign immunity or establish standing to sue any Defendant for two of the three alleged harms she wants remedied. Fed. R. Civ. P. 12(b)(1). Second, on the merits of the allegations, Issak has breached the statute of limitations, lacks a § 1983 cause of action against the IRB because it is not a person, fails to overcome the protections of qualified immunity, and fails to allege that IRB review violates her First Amendment rights or is an unconstitutional condition. Fed. R. Civ. P. 12(b)(6).

I. This Court Lacks Jurisdiction.

Federal courts lack Article III jurisdiction if defendants are protected by sovereign immunity

and plaintiffs lack standing. Issak has the burden to demonstrate subject matter jurisdiction for both doctrines. *Cartwright*, 751 F.3d at 759-60. She satisfies neither.²

A. Issak does not overcome the IRB's sovereign immunity.

Sovereign immunity protects the States from suit. *Alden v. Maine*, 527 U.S. 706, 715 (1999); *Hans v. Louisiana*, 134 U.S. 1, 14-15 (1890). “That immunity flows from the nature of sovereignty itself as well as the Tenth and Eleventh Amendments to the United States Constitution.” *Ernst v. Rising*, 427 F.3d 351, 358 (6th Cir. 2005). As a state agency, and not a person, the IRB is immune from suit under § 1983. *Will v. Michigan Dep’t of State Police*, 491 U.S. 58, 70-71 (1989).

There are several exceptions to a State’s sovereign immunity. *Ernst*, 427 F.3d at 358. Issak invokes only one, the exception that “immunity does not attach if the lawsuit is not against the State or an ‘arm of the State.’” *Id.*; Dkt. 34 ¶¶ 59-68. Issak claims that, even though UT is an arm of Tennessee with uncontested sovereign immunity, its IRB is not. Dkt. 34 ¶¶ 59-68. She is mistaken.

“[A]rm of the state” questions usually arise when considering whether a governmental entity is state or local. *Ernst*, 427 F.3d at 359. But this District has also applied the “arm of the state” factors when reviewing whether an entity is state or private. *Reece v. Doe Mountain Recreation Auth.*, No. 2:23-CV-00166-DCLC-CRW, 2025 WL 897978, at *4 (E.D. Tenn. Mar. 24, 2025). There are four factors courts consider: (1) “the State’s potential liability for a judgment against [the entity]”; (2) the State’s characterization of and control over the entity; (3) the State’s role in appointing members of the entity; and (4) the entity’s function “within the traditional purview” of state government. *Kreipke v. Wayne State Univ.*, 807 F.3d 768, 775 (6th Cir. 2015) (citation omitted). The first factor is the “foremost” or

² Issak also asks for a universal declaration that the IRB is unconstitutional. Dkt. 34, at 4 n.2, 46 ¶¶ (i)-(ii). To the extent that Issak seeks relief that goes further than necessary to remedy her alleged injury, she runs afoul of the jurisdictional limitations in the Supreme Court’s recent decision in *Trump v. CASA, Inc.*, 145 S. Ct. 2540, 2551-52 (2025). There, the Court made clear that Article III prohibits federal courts from issuing “declaratory [or] injunctive relief” that “directly interfere[s] with enforcement of” governmental regulations against non-parties. *Id.* at 2552 (quoting *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931 (1975)); see *id.* at 2563 (Thomas, J., concurring).

“most salient.” *Guertin v. State*, 912 F.3d 907, 937 (6th Cir. 2019). The other factors are also significant because “sovereign immunity protects not only a state’s purse but also its dignity.” *Id.* Each factor indicates the IRB is an arm of Tennessee and, therefore, immune from suit.

1. The IRB is a state-funded subsidiary of UT and, thus, a judgment against it would be paid by Tennessee. “[I]f a state’s . . . statutory law make[s] the state responsible for funding an entity, that reality makes the state potentially responsible for a judgment against it.” *Kreipke*, 807 F.3d at 775 (cleaned up, citation omitted); *Reece*, 2025 WL 897978, at *4 (same). Here, through two steps, Tennessee funds the IRB. First, Tennessee funds UT—it both finances UT with state revenue, Tenn. Code Ann. § 49-9-209(d)(1)(F), and provides that any revenue UT may receive “shall be state funds and shall be protected by the State’s sovereign immunity,” Tenn. Code Ann. § 9-1-103(b). Next, UT then uses its funds to pay for the compensation and salaries of IRB staff and employees as well as all other expenses necessary to operate the IRB. Ex. 7, Crawford Declaration ¶¶ 6-10.³ Because the funds that UT uses to pay the IRB are state funds, Tenn. Code Ann. § 9-1-103(b), any judgment against the IRB would be the responsibility of Tennessee, *Kreipke*, 807 F.3d at 775; *Reece*, 2025 WL 897978, at *4. Thus, this “foremost” and “salient” factor weighs in favor of the IRB’s sovereign immunity. *Guertin*, 912 F.3d at 937.

2. UT’s characterization of and control over the IRB indicates the IRB is a subsidiary state entity. If state law indicates an entity is a state entity, the State has control over the entity, and the State has veto power over the entity, it is a state entity. *Kreipke*, 807 F.3d at 777. UT’s treatment of the IRB checks each of these boxes, indicating it is a subsidiary protected by UT’s statutory grant of sovereign immunity. Tenn. Code Ann. § 20-13-102(b); *Rives v. University of Tennessee*, No. 24-5336, 2024 WL 5103829, at *3 (6th Cir. Dec. 13, 2024) (noting the “subsidiaries” of UT are “entitled to sovereign

³ Because Defendants bring a factual challenge to jurisdiction, the Court may consider documents outside of the Amended Complaint. *Ames*, 86 F.4th at 731.

immunity”).

UT characterizes the IRB as an “administrative unit” of UT. UT SOPs at 20, 22. UT has extensive control over the IRB. When “Tennessee law provides the mechanism for [an entity’s] structure and internal governance, its purpose, and affords its officers and directors all their powers having enacted its entire governing structure” then “Tennessee exercises significant control over” that entity. *See Reece*, 2025 WL 897978, at *4. UT’s SOPs do all of this for the IRB. UT SOPs at 22, 49-88.

UT also has veto power over the IRB. It is true, as Issak points out, that UT may not “approve research if it has not been approved or has been disapproved by the IRB.” UT SOPs at 49; Dkt. 34 ¶¶ 59-68. But, Issak ignores that UT has authority to “disapprove” research that has been approved by the IRB. *Id.* at 8-9, 21, 49; *see* 45 C.F.R. § 46.112. Besides, the bar on UT approving what the IRB has disapproved is not a strike against treating the IRB as an arm of the State. At times, to ensure that a university “provide[s] the highest quality education” and to “maintain the . . . reputation of the university,” a subsidiary of a state university must be “free from” outside influence. *Kreipke*, 807 F.3d at 778 (citation omitted). Despite this independence, the subsidiary still “remains a part of the government of the state.” *Id.* The IRB must have independence from outside forces to ensure that any approved research reflects the rigorous criteria it must apply in its review. UT SOPs, at 55, 68-75. But, with this measure of independence, the IRB still remains a part of UT and, thus, a part of the government of Tennessee. *Kreipke*, 807 F.3d at 778.

3. Issak correctly concedes that UT has the power to appoint members of the IRB. Dkt. 34 ¶ 63; UT SOPs at 20, 22, 50-51. So this factor also weighs against her.

4. Finally, the IRB serves two roles that are traditionally functions of state government. By instructing students in the proper methodology for human-subjects research, the IRB furthers “higher education,” which “is a function within the traditional purview of state government.” *Kreipke*, 807 F.3d at 779.

The IRB’s role in ensuring ongoing compliance with federal conditions on funding for research projects at UT—the very role Issak says proves it is neither a state nor local entity, Dkt. 34 ¶¶ 67—is also a core state function. From the dawn of our country, the Supreme Court has recognized that Congress may place conditions on federal funds distributed to the States. *Medina v. Planned Parenthood S. Atl.*, 145 S. Ct. 2219, 2230 (2025). In the modern era, this occurs in the form of spending-power legislation, which is “much in the nature of contract: in return for federal funds, the States agree to comply with the federally imposed conditions.” *Id.* at 2232 (citation omitted). Congress’s decision to condition distribution of federal funds on a State’s IRB creation and review is a classic exercise of this spending power. 42 U.S.C. § 289. UT’s IRB is, thus, a necessary component of Tennessee’s agreement with the federally imposed conditions. *See Medina*, 145 S. Ct. at 2230; UT’s FWA at 3. And Tennessee law demonstrates that agency cooperation with federal funding requirements is a core state function, requiring state agencies, including UT, to document the federal funding they receive for complying with spending-power statutes. Tenn. Code Ann. § 9-1-111(a)(1).

Thus, *every* “arm of the State” factor confirms that the IRB is protected by sovereign immunity and should be dismissed as a party.

B. Issak lacks standing.

To establish standing, plaintiffs “must satisfy the usual standards for injury in fact, causation, and redressability.” *Alliance*, 602 U.S. at 393-94. A plaintiff must show standing “for each claim [s]he seeks to press” and “for each form of relief sought.” *Waskul v. Washtenaw Cty. Cmty. Mental Health*, 900 F.3d 250, 253 (6th Cir. 2018) (citation omitted). Issak seeks relief from the following alleged injuries: (1) she is required to submit an application for her proposed research to the IRB for review, (2) she had to show her proposed research was culturally appropriate, and (3) the IRB has “unconstrained discretion” to review her application, which chilled her speech. Dkt. 34 ¶¶ 1-12. But the second alleged harm is not ongoing and the third was not caused by Defendants. So, Issak lacks standing for two of

her three alleged injuries.

1. Issak has not shown the cultural-appropriateness requirement is an ongoing injury.

To show an injury in fact, a plaintiff must establish that “it has suffered (or will suffer) a ‘concrete and particularized’” injury “that the requested remedy will redress.” *NAACP v. Lee*, 105 F.4th 888, 902 (6th Cir. 2024) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992)). When “a plaintiff seeks prospective relief such as an injunction, the plaintiff must establish a sufficient likelihood of future injury,” *Alliance*, 602 U.S. at 381 (emphasis added), that is “real, immediate, and direct,” *Davis v. Fed. Election Comm’n*, 554 U.S. 724, 734 (2008). Issak has not done any of this.

Issak says she is harmed because UT requires that her research be “culturally appropriate.” Dkt. 34 ¶¶ 5, 172-77. She seeks an injunction to avoid this requirement. *Id.* at 47 ¶¶ (ix)-(x). But Issak alleges no injury that would entitle her to prospective relief from this requirement. *Wright v. O’Day*, 706 F.3d 769, 772 (6th Cir. 2013). She admits that on June 3, 2024, she provided the IRB with a letter that showed her research was culturally appropriate. Dkt. 34 ¶ 95. And she does not allege that the IRB raised the issue again. Dkt. 34 ¶¶ 96-121. Nor would the record support that allegation. *See* Submissions Packet, at 185-86, 192-94, 270, 362-65, 470. With no threatened future injury, Issak lacks standing for prospective relief from this requirement. *Davis*, 554 U.S. at 734. Thus, Issak’s viewpoint-discrimination challenge to this requirement should be dismissed from each of her five claims.

2. Issak does not establish causation.

“[I]t is a bedrock principle that a federal court cannot redress ‘injury that results from the independent action of some third party.’” *Murthy v. Missouri*, 603 U.S. 43, 57 (2024) (citation omitted). Issak self-inflicted one of her alleged harms by voluntarily narrowing her research.

Issak says that IRB review is so “unconstitutionally unconstrained and unmoored” that it chilled her speech by causing her to narrow her proposed areas of study. Dkt. 34 ¶¶ 143, 148, 219, 2244. As discussed below, the IRB is heavily regulated, and UT does not concede that IRB review

violates Issak's First Amendment rights. *See infra* Part II.D. But, regardless, Defendants did not cause her to narrow her area of study. Any shift in the scope of Issak's research project was self-imposed, and "self-inflicted injuries are not fairly traceable to" Defendants. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 418 (2013). Issak narrowed her research to avoid the inconvenience of addressing the many inconsistencies and ambiguities in her research proposal. For example, Beebe asked Issak to "provide a rationale for interviewing employers," Submission Packet, at 46. Issak responded that the interviews would "gather comprehensive insights into [the employers'] viewpoints" and "varied perspectives" would "enhanc[e] the depth of the study." *Id.* at 50. Beebe explained that this response did not "clarify the study purpose as it relates to employers." *Id.* at 118. Issak then announced, "[t]he study will not involve interviews with employers." *Id.* at 124. Review of each of Beebe and Withrow's letters to Issak demonstrates that *not once* did either even imply she should narrow the scope of her research. Submissions Packet, at 46-48, 117-18, 120, 192-94, 270, 362-65, 470. Thus, Issak's harm was self-inflicted and all her arguments that depend on this injury, such as the prior-restraint challenge in all five claims and her third request for declaratory relief, should be dismissed.

II. Issak fails to state a claim upon which relief can be granted.

Issak fails to state a claim for five reasons. First, her claims are barred by the statute of limitations. Second, she lacks a cause of action to sue the IRB. Third, she fails to overcome the individual-capacity Defendants' qualified immunity. Fourth, she fails to allege a First Amendment violation. Fifth, she does not show IRB review is an unconstitutional condition.

When assessing these Rule 12(b)(6) arguments, the Court may consider a variety of extrinsic documents without converting the motion into one for summary judgment if the documents' "authenticity" and "relevance" are not disputed. *Diei v. Boyd*, 116 F.4th 637, 644 (6th Cir. 2024) (citations omitted). These documents include relevant matters of public record—such as the Belmont Report and UT's FWA and SOPs, *Hasanaj v. Detroit Pub. Sch. Cmty. Dist.*, 35 F.4th 437, 446 n.2 (6th

Cir. 2022), *cert. denied*, 143 S. Ct. 2560 (2023); documents that are not subject to reasonable dispute—again, like the Belmont Report and UT’s FWA and SOPs, *Passa v. City of Columbus*, 123 F. App’x 694, 697 (6th Cir. 2005); and materials referred to in the Amended Complaint that are central to its claims—such as UT’s SOPs, Issak’s Submissions Packet, and the email chains with Beebe and Swamy, *Clark v. Stone*, 998 F.3d 287, 296 (6th Cir. 2021). Finally, because the Amended Complaint refers to the “part[s] of a chain of communication” contained in the Submissions Packet and various emails that support her side but omits the parts that “doom” her arguments and characterization of the facts, the Court may consider the entire chain of communication in the Submissions Packet and cited emails. *L. Offs. of David Freydin, P.C. v. Chamara*, 24 F.4th 1122, 1126 n.1 (7th Cir. 2022); Fed. R. Evid. 106.

A. Issak has breached the statute of limitations.

The statute of limitations bars Issak’s claims. Section 1983 claims are governed by Tennessee’s one-year statute of limitations. Tenn. Code Ann. § 28-3-104(a)(1)(B); *Dibrell v. City of Knoxville*, 984 F.3d 1156, 1161 (6th Cir. 2021). This limitations period begins to run either “when the plaintiff has a complete and present cause of action”—the standard rule, or when the plaintiff first learns of the complete and present cause of action—the discovery rule. *Id.* at 1162 (noting it is unclear which rule applies to § 1983 claims). While noting the Supreme Court often applies the standard rule to § 1983 claims, the Sixth Circuit currently applies the discovery rule. *Reguli v. Russ*, 109 F.4th 874, 879 (6th Cir. 2024). “[I]n determining when the cause of action accrues” under the discovery rule, courts look “to what event should have alerted the typical lay person to protect his or her rights.” *Eidson v. Tenn. Dep’t of Children’s Servs.*, 510 F.3d 631, 635 (6th Cir. 2007). Under this rule, Issak is time barred.

In her overlapping First Amendment claims, Issak challenges UT’s requirement that her research go through IRB review, the IRB’s cultural-appropriateness requirement, and the amount of discretion UT has given the IRB to conduct this review. Dkt. 34. Issak likely learned (and certainly could have learned) of the IRB-review process and the scope of the IRB’s discretion long before

preparing and receiving approval of her dissertation proposal on November 13, 2023. Dkt. 34 ¶¶ 48, 56; *see HRPP - Research, Integrity and Assurance*, UTK.edu, <https://perma.cc/KQ9C-SLD3>; *International Research*, UTK.edu, <https://perma.cc/YF38-KZTF> (last accessed August 6, 2025). But in any event, documents referenced in the Amended Complaint confirm that she knew of these requirements and the scope of the IRB’s discretion by March 25, 2024. Dkt. 34 ¶ 202; Submissions Packet, at 46-49. And in her Amended Complaint Issak admits she knew about the IRB-review requirements and the scope of its discretion by May 17, 2024, and May 31, 2024. Dkt. 34 ¶¶ 85-93; Submissions Packet, at 117-19, 120; Beebe and Issak Email Chain – March 2024, at 1-6. Despite this, Issak did not sue until June 2, 2025—more than one year after even the most recent of these dates. Thus, her claims are time-barred. *See* Tenn. Code Ann. § 28-3-104(a)(1)(B).

While the Amended Complaint includes allegations about events in the IRB-review process that occurred after these dates, Dkt. 34 ¶¶ 120, those later events do not restart the clock. In unique circumstances, a statute of limitations is not a barrier if a defendant’s “wrongful conduct” is a pattern of behavior that continuously injures a plaintiff, and that continuing injury could be avoided by a change in conduct. *Eidson*, 510 F.3d at 635. This continuing violation is much like “hostile-work environment claims where the harm ‘cannot be said to occur on any particular day.’” *Goldsmith v. Sharrett*, 614 F. App’x 824, 829 (6th Cir. 2015) (quoting *Nat’l R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 115 (2002)). Most § 1983 claims do not resemble this kind of amorphous offense, so the Sixth Circuit “rarely extends” the continuing violations doctrine “to § 1983 actions.” *Sharpe v. Cureton*, 319 F.3d 259, 267 (6th Cir. 2003)

The alleged “wrongful conduct” Issak challenges is UT’s requirement that she work through an IRB-review process with an IRB that has a measure of discretion and requires culturally appropriate research. Dkt. 34 ¶¶ 2-12. This requirement was imposed at a discrete point in time, not through an amorphous practice of ongoing, diffuse discrimination like a hostile environment claim. *Sharpe*, 319

F.3d at 267 (citation omitted). Issak became subject to, and inherently consented to, this requirement when she voluntarily joined UT's Ph.D. program. And Issak learned the full scope of the requirement by at least March 25, 2024. Dkt. 34 ¶ 202; Submissions Packet, at 46-49. All allegations in the Amended Complaint about subsequent actions by Defendants "stem from" UT's decision to require IRB review for the type of research Issak wants to conduct. *Peterson v. Ostrander*, No. 17-2160, 2018 WL 4739692, at *3 (6th Cir. Apr. 6, 2018). These subsequent actions "are appropriately characterized as 'continuing ill effects,' which do not make out a continuing violation." *Eidson*, 510 F.3d at 637. Thus, all Issak's claims are subject to, and breach, the statute of limitations, so they should all be dismissed.

B. Issak lacks a cause of action to sue the IRB.

Even setting aside the protections of sovereign immunity, Issak lacks a cause of action to sue the IRB. When a federal-question claim is brought into court, there must be "a legislatively conferred cause of action [which] encompasses [that] particular plaintiff's claim." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 (2014); see *Keen v. Helson*, 930 F.3d 799, 802 (6th Cir. 2019). The only legislative cause of action that Issak relies on to sue the IRB is 42 U.S.C. § 1983. Dkt. 34, at 4 ¶ 13, 44. This statute gives a cause of action to sue a "person who, under the color of" state law causes a "deprivation of" federal rights. 42 U.S.C. § 1983. But the sub-entity of a state university is not a "person" who can be sued under § 1983. See, e.g., *McKenna v. Bowling Green State Univ.*, 568 F. App'x 450, 456 (6th Cir. 2014). Because the IRB is a sub-entity of a state university, see Part I.A, Issak lacks a cause of action for her claim against the IRB, and it should be dismissed as a party.

C. Issak does not overcome the individual-capacity Defendants' qualified immunity.

Qualified immunity bars Issak's damages claims against the individual-capacity defendants. The doctrine "shields government officials from monetary damages," *Ward v. Polite*, 667 F.3d 727, 742 (6th Cir. 2012), and can be raised in a Rule 12(b)(6) motion when the allegations in the complaint are inadequate, *Siefert v. Hamilton Cnty.*, 951 F.3d 753, 761-62 (6th Cir. 2020). Government officials are

protected from suit unless the answer is “yes” to “two questions: Did the offic[ials] violate [the plaintiff’s] constitutional rights? And did the governing caselaw clearly establish the violation when it occurred?” *Gibson v. Abate*, No. 24-1929, 2025 WL 1913247, at *1 (6th Cir. July 11, 2025).

The answer to the first question is “no” for reasons discussed below. *Infra* Part II.D. The answer to the second question is also “no.” “Proving that a constitutional right is clearly established is no easy task” *Fitzpatrick v. Hanney*, 138 F.4th 991, 995 (6th Cir. 2025). A plaintiff must meet two rigid requirements. “First, the rule establishing the right must be ‘settled,’ meaning that it is ‘dictated by controlling authority’ and not merely ‘suggested by then-existing precedent.’” *Id.* (quoting *District of Columbia v. Wesby*, 583 U.S. 48, 63 (2018)). “And second, the rule must ‘clearly prohibit the [official’s] conduct in the particular circumstances before him.’” *Id.* (quoting *Wesby*, 583 U.S. at 63). Essentially, the precedent must “be clear enough that every reasonable official would interpret it to establish the particular rule the plaintiff seeks to apply.” *Id.* (cleaned up, citation omitted). This standard “gives ample room for mistaken judgments by protecting all but the plainly incompetent or those who knowingly violate the law.” *Hunter v. Bryant*, 502 U.S. 224, 229 (1991) (cleaned up, citation omitted). “Absent a ‘beyond debate’ showing that the [officials] acted unconstitutionally, they receive immunity.” *Cunningham v. Blackwell*, 41 F.4th 530, 536 (6th Cir. 2022) (citation omitted).

Issak does not cite a single case even *suggesting* that IRB review violates the First Amendment. Dkt. 34. That is no surprise. The issues in this field of legal inquiry are rife with “ambiguity” and “can be difficult and confusing, even for lawyers, law professors, and judges.” *Radwan v. Manuel*, 55 F.4th 101, 120-22 (2d Cir. 2022) (citation omitted); *see also* Philip Hamburger, *The Inversion of Rights and Power*, 63 Buff. L. Rev. 731, 805 (2015) (noting that, as of 2015, no academic or university had challenged the constitutionality of IRB review in court). The upshot: Because Issak does not show a violation of a clearly established right, the individual-capacity Defendants are entitled to qualified immunity. *Sery v. Barach*, 815 F. App’x 58, 63-64 (6th Cir. 2020); *Andrews v. Hickman Cnty., Tenn.*, 700 F.3d 845, 853

(6th Cir. 2012). Thus, all six individual-capacity Defendants should be dismissed.

D. Issak’s constitutional claims lack merit.

As a threshold matter, while Issak calls her lawsuit an “as-applied challenge,” Dkt. 1 ¶ 1, “the label is not what matters,” *Doe v. Reed*, 561 U.S. 186, 194 (2010). Instead, “[t]he important point” for identifying the nature of a challenge is whether a plaintiff’s “claim and the relief that would follow . . . reach beyond the particular circumstances” of that plaintiff. *Id.* And here, Issak appears to challenge *all* applications of IRB review to social science research that is not federally funded, and she seeks a universal declaration that IRB review is a facially unconstitutional prior restraint on that research. Dkt. 34, at 2 ¶ 1, 4 ¶ 12 & n.2, 46 ¶¶ (i)-(ii). Issak, then, “must satisfy the ‘standards for a facial challenge to the extent of that reach.’” *Green Party of Tennessee v. Hargett*, 791 F.3d 684, 692 (6th Cir. 2015) (quoting *Reed*, 561 U.S. at 194). Facial challenges “often rest on speculation” and “threaten to short circuit the democratic process,” so the Supreme Court “has therefore made facial challenges hard to win.” *Moody v. NetChoice, LLC*, 603 U.S. 707, 723 (2024). First Amendment claims are no exception. There, too, plaintiffs must show (or at the pleading stage, allege) that the “unconstitutional applications” of a challenged governmental restriction “substantially outweigh its constitutional ones.” *Id.* Issak does not come close to satisfying this requirement. She alleges only that “the IRB Mandate has also chilled some other graduate students’ speech.” Dkt. 34 ¶ 149. That is not enough. *See Moody*, 603 U.S. at 723.

Issak’s as-applied claims fare no better. First, the challenged IRB requirements are subject only to highly deferential forms of scrutiny, which they easily survive. Second, even if some form of heightened scrutiny is applied, the IRB’s content-, speaker-, and viewpoint-neutral requirements should still be upheld. Third, for similar reasons, the IRB review is not a facially unconstitutional prior restraint on speech.

1. IRB review does not warrant heightened First Amendment Scrutiny.

The First Amendment prohibits the U.S. “Congress [from] mak[ing]” any “law . . . abridging the freedom of speech.” U.S. Const. amend. I. The Fourteenth Amendment extends these prohibitions to the States. *See Thornhill v. Alabama*, 310 U.S. 88, 95 (1940). Yet the rights protected by the First Amendment “are not, of course, without boundary.” *Citizens for Tax Reform v. Deters*, 518 F.3d 375, 379 (6th Cir. 2008). For that reason, some speech-related limitations do not demand heightened First Amendment review. The challenged IRB requirements fall into this category. First, the government may freely regulate conduct—even conduct carried out through speaking—without infringing on the First Amendment. Second, the educational context already affords the government great leeway to regulate speech without triggering heightened scrutiny, and this should be doubly true when a university regulates conduct.

1. “[I]t has never been deemed an abridgement of freedom of speech to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.” *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949). Instead, the First Amendment’s protections come into play when the government “directly regulate[s] speech.” *Otto v. City of Boca Raton*, 981 F.3d 854, 865 (11th Cir. 2020). Or, said another way, when it targets “speech as speech.” *McLemore v. Gumucio*, --- F.4th ---, 2025 WL 2319119 (6th Cir. Aug. 12, 2025) (quoting *Nat’l Inst. of Fam. & Life Advoc. v. Becerra* (NIFLA), 585 U.S. 755, 770 (2018)). This prohibited targeting occurs only when expression has been “target[ed] . . . because of its message.” *Lichtenstein v. Hargett*, 83 F.4th 575, 592 (6th Cir. 2023) (emphasis added); *id* at 588 (citing *R.A.V. v. St. Paul*, 505 U.S. 377, 385 (1992)); *see NRA v. Vullo*, 602 U.S. 175, 187 (2024); *NIFLA*, 585 U.S. at 766; *Sorrell v. INS Health, Inc.*, 564 U.S. 552, 564 (2011); *Simon & Schuster, Inc. v. Members of N.Y. State Crime Victims Bd.*, 502 U.S. 105, 116 (1991).

In practice, this means that “[s]tates may regulate . . . conduct, even though that conduct incidentally involves speech.” *Del Castillo v. Secretary*, 26 F.4th 1214, 1222 (11th Cir. 2022) (quoting *NI-FLA*, 585 U.S. at 768); see *Liberty Coins, LLC v. Goodman*, 748 F.3d 682, 697 (6th Cir. 2014); accord *United States v. Pinelli*, 890 F.2d 1461, 1472 (10th Cir. 1989). To be sure, a person’s “conduct” is “brought about through speaking and writing” in “most instances.” *Giboney*, 336 U.S. at 502; see *Rumsfeld v. F. for Acad. & Institutional Rts., Inc. (FAIR)*, 547 U.S. 47, 62 (2006). But merely “integrat[ing]” language into one’s conduct does not implicate core free-speech concerns. *Giboney*, 336 U.S. at 498; see *Nat’l Ass’n for Advancement of Multijurisdiction Practice v. Howell*, 851 F.3d 12, 20 (D.C. Cir. 2017); *Nat’l Ass’n for the Advancement of Multijurisdiction Prac. v. Castille*, 799 F.3d 216, 220-23 (3d Cir. 2015). Instead, Courts ask whether the government has directly targeted “expression,” whether conveyed through language or through unambiguous “symboli[sm].” *FAIR*, 547 U.S. at 61, 65 (quoting *United States v. O’Brien*, 391 U.S. 367, 376 (1968)); see *Lichtenstein*, 83 F.4th at 583-85. Government action not fitting that description receives “no heightened First Amendment scrutiny.” *EMW Women’s Surgical Ctr., P.S.C. v. Beshear*, 920 F.3d 421, 429 (6th Cir. 2019); see *Bevan & Assocs., LPA, Inc. v. Yost*, 929 F.3d 366, 374 (6th Cir. 2019).

The IRB-review process here fits that description to a tee. When the IRB reviews a research proposal, it looks at distinct criteria ranging from the research’s consent protocols to whether “the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.” 45 C.F.R. § 46.111(a); UT SOPs, at 55, 68-75. The IRB requires “additional safeguards” for “vulnerable subjects such as ‘economically or educationally disadvantaged persons.’” 45 C.F.R. § 46.111(b); UT SOPs, at 68. Likewise, the cultural-appropriateness requirement aims to avoid endangering international subjects in their unique legal and cultural contexts and encourages compliance with “the customs, practices, or standards of care where the research will be taking place.” UT SOPs, 235-36; Submissions Packet, at 263-64. These criteria focus on how a researcher’s *conduct*

will protect the research subjects. They have nothing to do with “censor[ing]” that researcher’s “descriptions and narratives.” *McLemore*, 2025 WL 2319119, *4.

UT, moreover, acted within its authority when it created these requirements. *McLemore*, 2025 WL 2319119, *4. As an academic institution, UT has “four essential freedoms”—“to determine for itself on academic grounds [1] who may teach, [2] what may be taught, [3] how it shall be taught, and [4] who may be admitted to study.” *Johnson-Kurek v. Abu-Absi*, 423 F.3d 590, 593 (6th Cir. 2005) (quoting *Sweezy v. New Hampshire*, 354 U.S. 234, 263 (1957) (Frankfurter J., concurring)); *Parate v. Isibor*, 868 F.2d 821, 827 (6th Cir. 1989). The IRB-review requirements encompass both “what” is taught—proper research protocols—and “how” it is taught—proposals are reviewed to ensure no violation of human rights.

While Issak makes much of the fact that she will use “verbal communication” and “ask questions” when conducting interviews, Dkt. 34 ¶¶ 128-30, a course of conduct does not trigger the First Amendment just because it will be “in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed,” *FAIR*, 547 U.S. at 62. Courts routinely uphold regulations of verbal conduct. They have upheld prohibitions against employers setting up signs “reading ‘White Applicants Only,’” requirements that law schools send “scheduling emails” to military recruiters, *Id.*, or most recently, requirements that auctioneers obtain licenses before “engag[ing] in speech” by practicing their trade, *McLemore*, 2025 WL 2319119, *4. They do so because, even though language is involved, the regulations do not target the verbal conduct’s messaging, which could trigger the First Amendment. *FAIR*, 547 U.S. at 62. Instead, they target the tasks accomplished by this verbal conduct—which does not. *Id.*; *Lichtenstein*, 83 F.4th at 582; *McLemore*, 2025 WL 2319119, *4.

Because the IRB-review requirements do “not implicate a suspect classification or fundamental right,” they receive only rational basis review. *McLemore*, 2025 WL 2319119, *4. They easily survive under that deferential standard. As set out below, the State has important interests in

preserving federal funding, protecting human research subjects, and educating students on proper research methodology. *Infra* Part II.D.2 IRB review is rationally connected to all these interests. In fact, these requirements would pass even heightened scrutiny. *Id.*

2. Deferential review is also warranted because schools already have “special leeway” to regulate student speech that “others may reasonably perceive as ‘bear[ing] the imprimatur of the school,’” so UT should have even greater leeway to regulate Issak’s conduct. *Mahanoy Area Sch. Dist. v. B. L. by & through Levy*, 594 U.S. 180, 187-88 (2021).⁴ Universities may “limit ‘student speech in school-sponsored expressive activities so long as their actions are reasonably related to legitimate pedagogical concerns.’” *Ward*, 667 F.3d at 733 (quoting *Hazelwood Sch. Dist. v. Kuhlmeier*, 484 U.S. 260, 273 (1988)). Inquiry into a university’s limitation on speech does not require courts “to balance the gravity” of the university’s “educational purpose” against a student’s “First Amendment right to free speech.” *Curry ex rel. Curry v. Hensiner*, 513 F.3d 570, 579-80 (6th Cir. 2008). It only requires “that the educational purpose behind the speech suppression be valid.” *Id.*; *Am. C.L. Union of Fla., Inc. v. Miami-Dade Cnty. Sch. Bd.*, 557 F.3d 1177, 1202-03 (11th Cir. 2009). Because schools already have special leeway to regulate student speech, they must have the same, if not more, leeway to regulate student conduct affiliated with the school.

Here, “special leeway” applies because Issak’s proposed research “bear[s] the imprimatur” of UT. *Mahanoy Area Sch. Dist.*, 594 U.S. at 187; *see* UT SOPs, at 8. She is enrolled in a doctoral program at UT and wants to conduct research in the UAE solely to qualify for her degree from UT. Dkt. 34 ¶¶ 54-58. When conducting this research, she would present herself as a researcher from UT and would even direct her research subjects to the UT IRB if they have questions about the study. Submissions

⁴ Though Supreme Court precedent in this area largely focuses on primary and secondary education, the Sixth Circuit does not find a “stop-go distinction between student speech at the high school and university levels.” *Ward*, 667 F.3d at 733-34.

Packet, at 349, 352, 457. And if her research efforts go awry, UT—not Issak—would face repercussions from the federal government. 45 C.F.R. §§ 46.122-23.

“[L]egitimate pedagogical concerns” motivate UT’s requirements that the IRB approve Issak’s research and ensure it is culturally appropriate. *Ward*, 667 F.3d at 733. UT is committed to teaching its students how to engage in well-structured research projects that respect the subjects studied and produce high-quality results. *HRPP Research, Integrity and Assurance*, UTK.edu, <https://perma.cc/KQ9C-SLD3>; UT SOPs, at 8, 26. IRB review and its cultural-appropriateness requirement are key to those educational goals, allowing UT to assess in advance whether a research project will produce coherent results without harming its subjects or violating international policies.

In a comparable case, *Brown v. Li*, a court found a “legitimate pedagogical purpose” in a thesis committee’s decision not to approve a thesis solely because its acknowledgments section was unprofessional. 308 F.3d 939, 947 (9th Cir. 2002). Writing a thesis, the court reasoned, is “fairly characterized as part of the curriculum.” *Id.* at 952 (cleaned up, citation omitted). This meant the First Amendment permitted the thesis to be “subject to a reviewing committee’s reasonable regulation.” *Id.* So, when the plaintiff bypassed the appropriate approval process and “prepared an assignment that did not comply with the [university’s] stated criteria,” his dissertation committee “acted well within their discretion, *and in conformity with the First Amendment*” when they declined to approve his noncompliant section. *Id.* (emphasis added). Their decision “was reasonably related to a legitimate pedagogical objective: teaching Plaintiff the proper format for a scientific paper.” *Id.* IRB review of Issak’s planned research is reasonably related to a similar pedagogical goal: teaching Issak how to conduct research for an anthropology dissertation that involves human subjects and international study. Thus, the IRB-review and cultural-appropriateness requirements do not violate the First Amendment. *Ward*, 667 F.3d at 733; *Curry ex rel. Curry*, 513 F.3d at 579-80.

That these requirements are widely publicized does Issak no favors. “When a university lays

out a program's curriculum or a class's requirements for all to see, it is the rare day when a student can exercise a First Amendment veto over them." *Ward*, 667 F.3d at 734. As a "prospective university student" at UT, Issak already had the "capacity to learn" what UT's doctoral research programs required "before applying to the school and before matriculating there." *Id.* Issak does not allege that any of the IRB-review requirements were kept from her. On the contrary, in the Amended Complaint, she relies on UT's SOPs directly and many of the online resources that contain or explain UT's publicly available SOPs. *See* Dkt. 34 ¶¶ 3, 64-65, 67, 70-73, 81-82, 144-145. Because Issak had easy access to the IRB-review and cultural-appropriateness requirements before applying to UT's doctoral program, and because those requirements are reasonably related to UT's legitimate pedagogical goals, Issak's First Amendment challenges to these requirements fail to state a claim.

2. IRB review passes muster, even under heightened review.

As explained above, the IRB-review process is subject to highly deferential review. The process targets only conduct, meaning that it need only be supported by a rational basis. And UT's "special leeway" to regulate speech bearing its "imprimatur" offers an independent justification for the IRB-review requirements regulating student conduct. Yet, even setting aside these protections, the requirements would survive any potentially applicable form of heightened First Amendment scrutiny.

The First Amendment jurisprudence offers many different forms of "heightened" scrutiny. *See Lichtenstein*, 83 F.4th at 596-98; *see also, e.g., Reed v. Town of Gilbert, Ariz.*, 576 U.S. 155, 163 (2015), (content-based speech restrictions); *McCullen v. Coakley*, 573 U.S. 464, 477 (2014) (restrictions to govern speech in traditional public fora); *Pleasant Grove City v. Summum*, 555 U.S. 460, 470 (2009) (restrictions to govern speech in limited public fora); *City of Renton v. Playtime Theatres*, 475 U.S. 41, 47 (1986) (time-, place-, and manner-of-speech restrictions); *Parker v. Com. of Ky., Bd. of Dentistry*, 818 F.2d 504, 509 (6th Cir. 1987) (restrictions to govern commercial speech); *O'Brien*, 391 U.S. at 376-77 (regulations targeting conduct that is also "symbolic speech"). The list also includes "vari[ous]"

different forms of “intermediate scrutiny.” *360 Virtual Drone Servs., LLC v. Ritter*, 102 F.4th 263, 275 n.5 (4th Cir. 2024). And the cases even “use[] the phrase ‘narrow tailoring’ to describe several different ‘means-ends’ tests.” *Lichtenstein*, 83 F.4th at 597. Choosing among these forms can prove challenging. Here, though, several can be rejected out of hand.

1. UT’s IRB-review process, contrary to Issak’s claims, does not warrant strict scrutiny. As a general matter, regulations of expressive conduct (something Issak has not even alleged) and conduct regulations that burden speech will receive—“at most”—intermediate scrutiny. *Id.* at 584; *see Free Speech Coal., Inc. v. Paxton*, 145 S. Ct. 2291, 2309 (2025) (noting that an incidental “burden” on speech is reviewed under “intermediate scrutiny”). To receive strict scrutiny, Issak would have to show that the challenged IRB requirements directly restrict her speech. As explained above, *see supra* Part II.D.1, she has not done so.

Issak’s only other path to strict scrutiny is to show that the challenged requirements, even though not *directly* restricting speech, nevertheless discriminate based on content or viewpoint, or among speakers. *Paxton*, 145 S. Ct. at 2302. To be sure, Issak does claim that the challenged requirements discriminate in these prohibited ways, *see* Dkt. 34 ¶¶ 8, 153-77, but an examination of the requirements themselves tells a different story. Start with content discrimination. Issak points out—correctly—that UT requires IRB review for research that will contribute to generalizable knowledge but not for targeted research, such as biographical investigations, that focus on “the specific individuals about whom the information is collected.” Dkt. 34 ¶¶ 73, 134, 153-77; 45 C.F.R. § 46.102(l)(1); UT SOPs, at 11. She says, too, that “Content based laws—those that target speech based on its communicative content—are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.” Dkt. 34 ¶ 161 (quoting *Town of Gilbert*, 576 U.S. at 163).

Issak’s bid for strict scrutiny runs aground on this speech-targeting requirement. Whatever the

challenged IRB requirements do, they do not treat speech differently “based on its communicative content.” *Contra id.* The requirements, recall, focus on the “purpose” for which Issak’s research findings will be used. *City of Austin, Texas v. Reagan Nat’l Advert. of Austin, LLC*, 596 U.S. 61, 74 (2022). Research conducted with the aim of contributing to “generalizable knowledge” requires IRB review. Research without that purpose requires none. The dividing line, in other words, is the “function or purpose” of the research, not the researcher’s speech. *City of Austin*, 596 U.S. at 74. Indeed, application of the generalizable-knowledge standard requires no consideration of the researcher’s speech at all—Issak could ask the *same* questions to the *same* participants and acquire the *same* answers without undergoing IRB review if those answers were to be used as part of a “biography or oral history.” Dkt. 34 ¶ 73 (citation omitted). The takeaway? The challenged IRB requirements draw a purpose-based line, not a content-based one. And when a regulation does “not even require investigation into what the [speaker] will be talking about” but instead “looks only to whether the [speaker] seeks” to accomplish a specific goal, the regulation is content neutral. *Zillow, Inc. v. Miller*, 126 F.4th 445, 460-61 (6th Cir. 2025).

Issak’s efforts to paint the challenged IRB requirements as impermissible speaker-based restrictions fall flat for essentially the same reason. She claims that the requirements treat historians and journalists differently from anthropologists. Dkt. 34 ¶¶ 165-70. But IRB-review is not triggered by the speaker at all; it’s triggered by the speaker’s research goal of contributing to generalizable knowledge. Journalists and historians who seek to use systematic investigation to contribute to generalizable knowledge would have to go through IRB review just like Issak. 45 C.F.R. § 46.102(l)(1); UT SOPs, at 11. Indeed, HHS explained as much when it amended the IRB regulations in 2018. *Supra* p. 3. Setting that threshold failure aside, whether a challenged requirement distinguishes between speakers “is only the beginning—not the end—of the inquiry.” *Zillow, Inc.*, 126 F.4th at 462 (cleaned up, citation omitted). A court would still need to determine “whether a drawn [speaker] distinction

evinces a preference among the topics discussed or the ideas or messages expressed.” *Id.* (cleaned up, citation omitted). Issak does not show that the challenged requirements “embed[] any content preference.” *Id.* Again, the requirements draw only *purpose*-based distinctions.

Issak’s final route to strict scrutiny—showing that the challenged requirements unconstitutionally discriminate based on viewpoint—fares no better. Her viewpoint-discrimination argument hinges on the IRB’s cultural-appropriateness requirement. *See* Dkt. 34 ¶¶ 172-77. This requirement poses no constitutional problem. The government, to be sure, “must abstain from regulating speech when the specific motivating ideology or the opinion or perspective of the speaker is the rationale for the restriction.” *Rosenberger v. Rector & Visitors of Univ. of Virginia*, 515 U.S. 819, 829 (1995). But that is not what this requirement does. It restricts no speech, *see supra* Part II.D.1, much less an “ideology” or “perspective.” Rather, it ensures “adequate provisions are in place to protect the rights and welfare” of international research subjects—which may not be the same rights as United States research subjects due to legal and cultural differences. UT SOPs, at 235-36. And here, the requirement meant only that Issak needed to clarify whether “ethics committee approval” from a foreign institution was required for her overseas research. Submissions Packet, at 48, 117. Issak does not explain how this requirement discriminated against her unique perspective, nor does she even allege that researchers with different perspectives on the same issues have received more favorable treatment. That failure to identify a favored viewpoint is fatal to her viewpoint-discrimination theory. *Cf. Hartman v. Thompson*, 931 F.3d 471, 480 (6th Cir. 2019) (rejecting a viewpoint-discrimination claim where a plaintiff could point to no group with an opposing viewpoint who received more favorable treatment); *Viewpoint Neutrality Now! v. Regents of Univ. of Minnesota*, 516 F. Supp. 3d 904, 923 (D. Minn. 2021) (same).

2. With strict scrutiny off the table, intermediate scrutiny is all that remains. Intermediate scrutiny, as the Supreme Court recently observed, is not “toothless,” but is “deferential.” *Paxton*, 145

S. Ct. at 2316. It ensures that “legislatures do not use ostensibly legitimate purposes to disguise efforts to suppress fundamental rights.” *Id.* A speech regulation will survive intermediate scrutiny “if it ‘advances important governmental interests unrelated to the suppression of free speech and does not burden substantially more speech than necessary to further those interests.’” *Id.* at 2317 (quoting *Turner Broadcasting System, Inc. v. F.C.C.*, 520 U.S. 180, 189 (1997)).

The IRB-review and cultural-appropriateness requirements easily survive under this standard. These requirements further many important interests wholly unrelated to suppressing speech. *Paxton*, 145 S. Ct. at 2317. First, UT committed to HHS in its FWA that it would apply the ethical principles of the Belmont Report to all UT-funded research projects. UT FWA, at 1. And the Belmont Report’s “general rule” is that *all* research activities involving human subjects should “undergo review.” Belmont Report, at 4. Second, the Report emphasizes that “[w]hen vulnerable populations,” particularly “racial minorities” or “the economically disadvantaged” are “involved in research, the appropriateness of involving them should itself be demonstrated.” *Id.* at 9. Issak concedes that her research subjects are vulnerable, so she should have to justify her plan. Submissions Packet, at 10-15, 25, 27. Third, IRB review is an educational tool that supports UT’s mission of “foster[ing] a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of” the university. UT SOPs, at 8. Finally, the cultural-appropriateness requirement ensures that “adequate provisions are in place to protect the rights and welfare of” foreign research subjects. UT. SOPs, at 235-36.

The requirements are also sufficiently narrow and do not burden more speech than necessary to further the government interests involved. *Paxton*, 145 S. Ct. at 2317. These requirements do not apply to all research—they apply to research that poses unique risks to human subjects and exclude investigative efforts that have a separate “ethical requirement . . . to provide an accurate and evidence-based portrayal of the individuals involved.” 82 Fed. Reg. at 7174-75. The IRB-review process is

designed to ensure excellent, responsible, and respectful research without constraining any messages in the research, 45 C.F.R. § 46.111; UT SOPs, at 49, 55-56, so any effect on speech is an incidental result “necessary to further” these interests, *Paxton*, 145 S. Ct. at 2317. And the cultural-appropriateness requirement, for its part, ensures proper respect is given to subjects of international studies that may have different needs and expectations without constraining the messaging in the research. UT SOPs, at 235-36. The challenged requirements, in short, are appropriately tailored.

At bottom, the challenged IRB requirements pass muster under intermediate scrutiny. They further an array of important government interests, none of which are at all related to the suppression of expression, and they are carefully tailored to do so without burdening more speech than necessary. That conclusion, moreover, does not depend on this Court’s “agreement” that the challenged requirements are “the most appropriate method” for furthering these interests. *Paxton*, 145 S. Ct. at 2317 (citation omitted). Thus, even if this Court considers heightened scrutiny, the challenged IRB requirements do not violate Issak’s First Amendment rights.

3. IRB review is not a facially unconstitutional prior restraint.

Issak’s prior-restraint claim fails for the same reasons as her other claims: The challenged requirements do not restrict her speech at all, and even if scrutinized, they easily survive heightened scrutiny. Issak disagrees. She maintains that, because the IRB has “unfettered” discretion to review her research and she “cannot begin her research until the IRB reviews it,” the IRB-review requirement “is an unconstitutional prior restraint” that chills her speech. Dkt. 34, at ¶ 7, 4 ¶ 12 & n.2; 23-25 ¶¶ 135-49, 46 ¶¶ (i)-(ii). She is mistaken on every point.

“A ‘prior restraint’ exists when *speech* is conditioned upon the prior approval of public officials.” *Nightclubs, Inc. v. City of Paducah*, 202 F.3d 884, 889 (6th Cir. 2000) (emphasis added). “Prior restraints are presumptively invalid because of the risk of censorship associated with the vesting of *unbridled* discretion in government officials and the risk of indefinitely suppressing permissible *speech*

when a licensing law fails to provide for the prompt issuance of a license.” *Int’l Outdoor, Inc. v. City of Troy, Michigan*, 974 F.3d 690, 697 (6th Cir. 2020) (emphasis added). “To be constitutional, a prior restraint must be content-neutral, narrowly tailored to serve a significant governmental interest, and leave open ample alternatives for communication.” *Id.* “It must also not delegate overly broad licensing discretion to official decision-makers.” *Id.* at 698. And the “decision whether or not to grant a permit [to speak] must be made within a specified, brief period” during which status quo is preserved. *Id.*

The challenged IRB requirements are a far cry from an unconstitutional prior restraint. “The fundamental objection to systems of prior restraint is that they create a risk of government censorship of expressive activity”—i.e., speech. *Schmitt v. LaRose*, 933 F.3d 628, 638 (6th Cir. 2019). But as explained above, *see supra* Part II.D.1, IRB review targets conduct, not speech. Said another way, it regulates *how* Issak will conduct her research; not the messages she conveys. It follows that the challenged requirements are “not a prior restraint.” *Schmitt*, 933 F.3d at 638. Beyond that, the requirements are content neutral, carefully tailored, and leave open ample channels for communication. Indeed, UT does not (and could not) prevent Issak from conducting research in UAE or publishing her findings. IRB review does not stop Issak from flying to the UAE and speaking with whom she wants when she wants. UT only requires that she go through IRB review if she intends to conduct this research in UT’s name. *See* UT SOPs, at 8; *Supra* pp. 25-26.

Nor is IRB review standardless and temporally unlimited. IRB review of proposed research is dictated by detailed “approval criteria” set out in federal regulations. UT SOPs, at 55, 67-68; 45 C.F.R. § 46.111(a)-(b). The fact that “[r]eviewing officials may strengthen requirements and/or conditions, or add other modifications before approval,” Dkt. 34 ¶ 144 (quoting UT SOPs, at 50), changes nothing. This cherry-picked language appears in a 241-page document that painstakingly details the purpose of IRB review and the constraints on its discretion to approve, require modification of, or deny a research project. *See, e.g.*, UT SOPs, at 68-75. What is more, full IRB review of a complete

application occurs during a brief, specified period. The IRB usually meets once a month. UT SOPs, at 64. Completed research projects will be considered for review if they are submitted approximately ten business days before that meeting. *Id.* at 64-65; Submissions Packet, at 48, 118, 194, 365. And at that meeting the IRB will vote on the submitted projects. UT SOPs, at 65-67. Taken together, these features of the IRB-review process confirm that it is not an unconstitutional prior restraint.

E. IRB review is not an unconstitutional condition.

Finally, Issak challenges IRB review as an unconstitutional condition on her obtaining a Ph.D. Dkt. 34 ¶¶ 150-52. This claim is premised on a flawed understanding of the unconstitutional-conditions doctrine and fails regardless because IRB review does not violate her rights.

“The United States Constitution does not contain an Unconstitutional Conditions Clause.” *Planned Parenthood of Greater Ohio v. Hodges*, 917 F.3d 908, 911 (6th Cir. 2019). But, courts recognize that a “government may not deny an individual a benefit, even one an individual has no entitlement to, on a basis that infringes his constitutional rights.” *Id.* However, this doctrine “involves situations” where a government condition “effectively prohibit[s] the recipient [of a benefit] from engaging in the protected conduct outside the scope of the [governmentally] funded program.” *Rust v. Sullivan*, 500 U.S. 173, 197(1991). To impose an unconstitutional condition, a government must have “coerce[d]” individuals “into giving . . . up” their rights entirely. *Planned Parenthood of Greater Ohio*, 917 F.3d at 912.

UT’s IRB review process does not coerce Issak to give up her rights entirely—it does not prohibit Issak’s research. If she chooses to ignore the IRB-review requirements, she can still go to UAE and conduct the research “outside the scope” of her dissertation program. *Rust*, 500 U.S. at 197. Thus, the unconstitutional-conditions doctrine does not apply to this situation. *Id.* But, even under that doctrine, because the IRB-review requirement does not violate the First Amendment, there is no infringement on Issak’s constitutional rights. *Supra* Part II.D.1-3.

The First Amendment attacks fail from every angle. The IRB does not target Issak’s speech,

much less impose content-, speaker-, or viewpoint-based restrictions on her. It regulates conduct in a way that is narrowly targeted to further a compelling state interest. And, consequently, IRB review is neither a prior restraint nor an unconstitutional condition. All claims should be dismissed.

CONCLUSION

For these reasons, Defendants' motion to dismiss should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 2, 2025, a copy of the foregoing was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties below:

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